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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,091	03/19/2001	Walter J. Ledergerber	263/103	2870
34263	7590	07/02/2004	EXAMINER	
O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/813,091	Applicant(s) LEDERGERBER, WALTER J.	
	Examiner DAVID J ISABELLA	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,13,94-98,110,112-114,122 and 158-169 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1,13,94-98,110,112-114 and 158-169 is/are rejected.
 7) ☒ Claim(s) 122 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

Claims 1,13,94-98,110,112-114,122,158-169 are pending for action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 163,165-169 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claims 166-169, the combination of a channeled sheet and holes is not clearly set forth in the original specification. While figure 12 shows the embodiment of a channeled sheet, it does not show the combination of the channels and the holes as shown in figure 11. Conversely, figure 11 shows the sheet to have holes formed therein but the specification is silent as to the sheet also being channeled. In the original specification, figure 12 is described as a perspective view of detail of PTFE sheet material with a partial thickness pattern of simple cuts and/or channels which results in numerous individual villi of PTFE and great irregularity of the surface of the material. Additional patterns of cuts or troughs may be made along any other axis as indicated, for example by the arrows. In column 8 lines 10-19, applicant defines the covering as a single sheet of PTFE with

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appropriate cuts 48 to permit stretching. The main body of the specification lacks any further description of figure 12. There is no positive nexus between the sheet as used in figure 11 and the sheet as embodied in figure 12. Absent the establishment that the sheet embodied in figure 12 and the sheet shown in figure 11 are one and the same, applicant may not craft claims to the combination of each feature. Claim 169, there is no support for the channel pattern to be random.

Claims 163 and 165 defines the cuts as being non-colinear with the channels and perpendicular to the channels, respectively. Nowhere in the specification is there support as to how the cuts are formed in the sheet. The specification merely illustrates a sheet with a plurality of channels formed therein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 13, 94-98, 110, 112-114, 158-165 are rejected under 35 U.S.C. 102(e) as being anticipated by Campbell et al (4743480).

An implantable sheet comprising a sheet of ePTFE having a non-textured first surface and a textured second surface including a plurality of continuous parallel channels with a plurality of ridges disposed between the channels is disclosed by Campbell, et al (see columns 2 and 3).

The added limitation of “channels being formed by cutting the second surface of the sheet” is directed to a method step. In so far as broadly worded it does not appear that the method of manufacture results in a different structural sheet. Examiner contends that the sheet as claimed is structurally identical to the sheet as disclosed by Campbell, et al.

Claim 13 does not preclude the first surface being non-textured. The added limitation of “channels being formed by cutting the second surface of the sheet” is directed to a method step. In so far as broadly worded it does not appear that the method of manufacture results in a different structural sheet. Examiner contends that the sheet as claimed is structurally identical to the sheet as disclosed by Campbell, et al.

Claim 94, since the bottom of the channel of the die is not planar the resulting structure of the tube would have a cross sectional dimension of varying width.

Claim 95, see discussion to claim 1 supra.

Claims 96-98,101, as broadly worded the features as claimed is disclosed by Campbell, et al.

Claim 112, see figure 1 for dimensional relationship of troughs and ridges.

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Claims 113 and 114, the body of the claims fails to set forth additional structure to perform the intended function of tissue ingrowth and disorganization of scar tissue formation. Based on the structure of the device as set forth in claim 1, the device of Campbell, et al meets the limitation thereof.

Claims 158-161 fails to distinguish over the structured device of Campbell, et al.

Claim 162, see channels of Campbell, et al.

Claim 163, see villi between channels.

Claims 163 and 164, The claims are directed to steps of manufacture. In so far as broadly worded it does not appear that the method of manufacture results in a different structural sheet. Examiner contends that the sheet as claimed is structurally identical to the sheet as disclosed by Campbell, et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 13, 94-98, 110, 112-114, 158-165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung (4034751) in view of Campbell et al (4743480) or Milkulich et al (4651721).

Hung discloses an implantable sheet comprising a sheet of polymer having a non-textured first surface and a textured second surface including a plurality of continuous parallel channels with a plurality of ridges disposed between the channels. The polymer may be various polymer materials including PTFE. It is not clear if ePTFE is included in this grouping however, ePTFE was not discovered until the early 1970 and it's use since that time as an equivalent material for use to make implantable devices is well documented. If not inherent in the material of Hung, to use ePTFE as a material for making implantable devices due to it's superior properties including directional strength and hoop strength, would have been obvious from the teachings of either of Campbell et al or Milkulich et al. The added limitation of "channels being formed by cutting the second surface of the sheet" is directed to a method step. In so far as broadly worded it does not appear that the method of manufacture results in a different structural sheet. Examiner contends that the sheet as claimed is structurally identical to the sheet as disclosed by Campbell, et al.

Claim 13 does not preclude the first surface being non-textured.

Claim 95, see discussion to claim 1 supra.

Claims 96-98,101, as broadly worded the features as claimed is disclosed by Campbell, et al.

Claim 112, see figure 1 for dimensional relationship of troughs and ridges.

Claims 113 and 114, the body of the claims fails to set forth additional structure to perform the intended function of tissue ingrowth and disorganization of scar tissue

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formation. Based on the structure of the device as set forth in claim 1, the device of Campbell, et al meets the limitation thereof.

Claims 158-161 fails to distinguish over the structured device of Campbell, et al.

Claim 162, see channels of Campbell, et al.

Claim 163, see villi between channels.

Claims 163 and 164, The claims are directed to steps of manufacture. In so far as broadly worded it does not appear that the method of manufacture results in a different structural sheet. Examiner contends that the sheet as claimed is structurally identical to the sheet as disclosed by Campbell, et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 166-169 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell, et al or Hung, respectively as applied to claim 1 above, and further in view of either of Kochauf (4209921) or Suzuki (4559254). The creation of a combination of channels and through holes in a PTFE sheeting is taught by each of Kochauf and Suzuki. To provide the channeled sheeting of either of Campbell or Hung with through holes would have been obvious to one with ordinary skill in the art at the time of the invention based on manufacturing requirements. A sheeting exhibiting the combination

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with channels and through holes was known at the time of the invention thereof and the combination in a ePTFE sheeting would have been obvious to one with ordinary skill in the art based on the teachings of either of Suzuki or Kochauf.

Allowable Subject Matter

Claim 122 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 4/28/2004 have been fully considered but they are not persuasive. The added limitation of "channels being formed by cutting the second surface of the sheet" is directed to a method step. In so far as broadly worded it does not appear that the method of manufacture results in a different structural sheet. Examiner contends that the sheet as claimed is structurally identical to the sheet as disclosed by Campbell, et al.

Applicant's arguments with respect to claims 162-169 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DAVID J ISABELLA** whose telephone number is 703-308-3060. The examiner can normally be reached on **MONDAY-FRIDAY**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **CORRINE MCDERMOTT** can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
June 29, 2004